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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Benny Bang-Andersen, et al.		
Serial No.:	10/551,870	Examiner:	David K. O'Dell
Filed:	November 16, 2005	Group Art Unit:	1625
Confirmation No.:	2040		
For:	4-(2-Phenyloxyphenyl)-piperidine or -1,2,3,6-tetrahydropyridine derivatives as serotonin reuptake inhibitors.		

May 15, 2008

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF THE SUBSTANCE OF THE APRIL 15, 2008 INTERVIEW

Applicants respectfully request this Statement of the Substance of the April 15, 2008 Interview (the "Statement") with regard to the merits of the above-identified application be made of record.

The due date to file the Statement is May 15, 2008. Accordingly, this Statement is being timely filed. No fee is deemed necessary in connection with the filing of this Statement; however, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 503201.

Summary begins on page 2 of this paper.
Remarks begin on page 5 of this paper.

SUMMARY

Interview:

(1) Interview date: April 15, 2008

(2) Interview type: Personal

Participants:

(3) Examiner(s): Rita J. Desai and David O'Dell

(4) Applicant's Representative(s): Stephen G. Kalinchak and Margaret M. Buck.

Details:

(5) Claims discussed: All claims

(6) Identification of prior art:

for 35 U.S.C. §103(a)

- Elliot, et al. PCT/IB00/00108, in view of
- Wang, S., et al. J. Med. Chem. 2000, 43, 351-360, or
- Tamiz, A.P., et al. J. Med. Chem. 2000, 43, 1215-1222, or
- Sakamuri, E., et al. Biorg. Med. Che,. Lett. 2001, 11, 495-500;

AND

- Martin, et al. J. Med. Chem. 1979, 22, 1347-1354, in view of
- Silverman, R.B. The Organic Chemistry of Drug Design and Drug Action. 1992, Academic: New York, pg 19, in further view of
- Elliot, et al. PCT/IB00/00108.

Substance of Interview:

During the Interview, Applicants' representatives focused on the rejection of the method of treatment claims under 35 U.S.C. 112, first paragraph. Specifically,

Applicants representatives urged that the rejection appeared tantamount to a requirement on Applicants to perform human clinical trials. Such a standard for patentability in the pharmaceutical arts, whether under the guise of 35 U.S.C. 101 or 35 U.S.C. 112, first paragraph, does not exist in the law or in any written United States Patent & Trademark Office policy. Indeed, MPEP 2107.03, which relates to establishment of utility under Section 101, states:

> Office personnel should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders . . . . Before a drug can enter human clinical trials, the sponsor, often the applicant, must provide a convincing rationale to those especially skilled in the art (e.g., the Food and Drug Administration) that the investigation may be successful . . . . [emphasis in original]

Applicants' representatives further asserted that evidence of dual and triple uptake inhibitors are expected to be useful for treatment of the claimed disease states that appears in public literature. A search of public databases has revealed that dual and triple uptake inhibitors of the serotonin, norepinephrine and dopamine transporters are reportedly under study by no less than eleven significant companies in the pharmaceutical industry. Those compounds under study are shown below:

Company	Compound	MOA
Biovail		
	bupropion controlled release	NA/DA reuptake inhib
BMS / Albany		
	Pre-clinical projects	5HT/NA/DA reuptake inhib
Dov		
	Dov102677	5HT/NA/DA reuptake inhib
	Dov216303	5HT/NA/DA reuptake inhib
	Dov21947	5HT/NA/DA reuptake inhib
Dynogen		
	DDP225	NA reuptake inhib / 5HT3 antag
Fabre-Kramer		
	TGBA01AD	5HT reuptake inhib / H1 antag
Johnson & Johnson		
	dapoxetine	5HT/NA reuptake inhib
	J&J28583867	5HT reuptake inhib / H3 antag
Lilly		
	LY2124275	NA reuptake inhib
	LY2216684	NA reuptake inhib
	Pre-clinical projects	5HT/NA reuptake inhib
Neurosearch / GSK		

	tesofensine	5HT/NA/DA reuptake inhib
	NS2359 / GSK372475	5HT/NA/DA reuptake inhib
Pierre Fabre		
	F-2695	5HT/NA reuptake inhib
Sepracor		
	SEP-225289	5HT/NA/DA reuptake inhib
	SEP-227162	5HT/NA reuptake inhib
	Pre-clinical projects	5HT/NA/DA reuptake inhib
Wyeth		
	des-Venlafaxine	5HT / NA reuptake inhib

Respectfully, Applicants' representatives submitted that random and speculative comments about efficacy and safety pulled from a few references in the rejection are improper under the MPEP, and further simply carry no weight against the connection to disease established for the dual mechanism of Applicants' invention.

No agreement on these issues was reached during the interview.

REMARKS

Applicants maintain that this Statement is complete and accurate regarding the substance of the April 15, 2008 Interview, and respectfully request the Statement is made of record in connection with the present application.

If a telephone interview would be of assistance to the Examiner's review of this Statement, the undersigned invites the Examiner to telephone the number provided below.

Respectfully submitted,

/ Stephen G. Kalinchak, Reg. # 38,747/

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